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NOTICE OF ALLOWANCE AND FEE(S) DUE

7590 05/14/2009

Chiron Corporation
Intellectual Property R440
PO Box 8097
Emeryville, CA 94662-8097

EXAMINER

DEVI, SARVAMANGALA J N

ART UNIT

PAPER NUMBER

1645

DATE MAILED: 05/14/2009

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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09/674,546

11/04/2002

Claire Fraser

PP00365.301

9020

TITLE OF INVENTION: NEISSERIA MENINGITIDIS ANTIGENS AND COMPOSITIONS

APPLN. TYPE	SMALL ENTITY	ISSUE FEE DUE	PUBLICATION FEE DUE	PREV. PAID ISSUE FEE	TOTAL FEE(S) DUE	DATE DUE
nonprovisional	NO	\$1510	\$0	\$1440	\$1510	08/14/2009

THE APPLICATION IDENTIFIED ABOVE HAS BEEN EXAMINED AND IS ALLOWED FOR ISSUANCE AS A PATENT. PROSECUTION ON THE MERITS IS CLOSED. THIS NOTICE OF ALLOWANCE IS NOT A GRANT OF PATENT RIGHTS. THIS APPLICATION IS SUBJECT TO WITHDRAWAL FROM ISSUE AT THE INITIATIVE OF THE OFFICE OR UPON PETITION BY THE APPLICANT. SEE 37 CFR 1.313 AND MPEP 1308.

THE ISSUE FEE AND PUBLICATION FEE (IF REQUIRED) MUST BE PAID WITHIN THREE MONTHS FROM THE MAILING DATE OF THIS NOTICE OR THIS APPLICATION SHALL BE REGARDED AS ABANDONED. THIS STATUTORY PERIOD CANNOT BE EXTENDED. SEE 35 U.S.C. 151. THE ISSUE FEE DUE INDICATED ABOVE DOES NOT REFLECT A CREDIT FOR ANY PREVIOUSLY PAID ISSUE FEE IN THIS APPLICATION. IF AN ISSUE FEE HAS PREVIOUSLY BEEN PAID IN THIS APPLICATION (AS SHOWN ABOVE), THE RETURN OF PART B OF THIS FORM WILL BE CONSIDERED A REQUEST TO REAPPLY THE PREVIOUSLY PAID ISSUE FEE TOWARD THE ISSUE FEE NOW DUE.

HOW TO REPLY TO THIS NOTICE:

I. Review the SMALL ENTITY status shown above.

If the SMALL ENTITY is shown as YES, verify your current SMALL ENTITY status:

A. If the status is the same, pay the TOTAL FEE(S) DUE shown above.

B. If the status above is to be removed, check box 5b on Part B - Fee(s) Transmittal and pay the PUBLICATION FEE (if required) and twice the amount of the ISSUE FEE shown above, or

If the SMALL ENTITY is shown as NO:

A. Pay TOTAL FEE(S) DUE shown above, or

B. If applicant claimed SMALL ENTITY status before, or is now claiming SMALL ENTITY status, check box 5a on Part B - Fee(s) Transmittal and pay the PUBLICATION FEE (if required) and 1/2 the ISSUE FEE shown above.

II. PART B - FEE(S) TRANSMITTAL, or its equivalent, must be completed and returned to the United States Patent and Trademark Office (USPTO) with your ISSUE FEE and PUBLICATION FEE (if required). If you are charging the fee(s) to your deposit account, section "4b" of Part B - Fee(s) Transmittal should be completed and an extra copy of the form should be submitted. If an equivalent of Part B is filed, a request to reapply a previously paid issue fee must be clearly made, and delays in processing may occur due to the difficulty in recognizing the paper as an equivalent of Part B.

III. All communications regarding this application must give the application number. Please direct all communications prior to issuance to Mail Stop ISSUE FEE unless advised to the contrary.

IMPORTANT REMINDER: Utility patents issuing on applications filed on or after Dec. 12, 1980 may require payment of maintenance fees. It is patentee's responsibility to ensure timely payment of maintenance fees when due.

PART B - FEE(S) TRANSMITTAL

**Complete and send this form, together with applicable fee(s), to: Mail Mail Stop ISSUE FEE
Commissioner for Patents
P.O. Box 1450
Alexandria, Virginia 22313-1450
or Fax (571)-273-2885**

INSTRUCTIONS: This form should be used for transmitting the ISSUE FEE and PUBLICATION FEE (if required). Blocks 1 through 5 should be completed where appropriate. All further correspondence including the Patent, advance orders and notification of maintenance fees will be mailed to the current correspondence address as indicated unless corrected below or directed otherwise in Block 1, by (a) specifying a new correspondence address; and/or (b) indicating a separate "FEE ADDRESS" for maintenance fee notifications.

CURRENT CORRESPONDENCE ADDRESS (Note: Use Block 1 for any change of address)

7590

05/14/2009

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Emeryville, CA 94662-8097

Note: A certificate of mailing can only be used for domestic mailings of the Fee(s) Transmittal. This certificate cannot be used for any other accompanying papers. Each additional paper, such as an assignment or formal drawing, must have its own certificate of mailing or transmission.

Certificate of Mailing or Transmission

I hereby certify that this Fee(s) Transmittal is being deposited with the United States Postal Service with sufficient postage for first class mail in an envelope addressed to the Mail Stop ISSUE FEE address above, or being facsimile transmitted to the USPTO (571) 273-2885, on the date indicated below.

(Depositor's name)
(Signature)
(Date)

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nonprovisional	NO	\$1510	\$0	\$1440	\$1510	08/14/2009

EXAMINER	ART UNIT	CLASS-SUBCLASS
DEVI, SARVAMANGALA J N	1645	530-350000

1. Change of correspondence address or indication of "Fee Address" (37 CFR 1.363).

☐ Change of correspondence address (or Change of Correspondence Address form PTO/SB/122) attached.

☐ "Fee Address" indication (or "Fee Address" Indication form PTO/SB/47; Rev 03-02 or more recent) attached. **Use of a Customer Number is required.**

2. For printing on the patent front page, list

(1) the names of up to 3 registered patent attorneys or agents OR, alternatively, 1 _____

(2) the name of a single firm (having as a member a registered attorney or agent) and the names of up to 2 registered patent attorneys or agents. If no name is listed, no name will be printed. 2 _____

3 _____

3. ASSIGNEE NAME AND RESIDENCE DATA TO BE PRINTED ON THE PATENT (print or type)

PLEASE NOTE: Unless an assignee is identified below, no assignee data will appear on the patent. If an assignee is identified below, the document has been filed for recordation as set forth in 37 CFR 3.11. Completion of this form is NOT a substitute for filing an assignment.

(A) NAME OF ASSIGNEE

(B) RESIDENCE: (CITY and STATE OR COUNTRY)

Please check the appropriate assignee category or categories (will not be printed on the patent) : ☐ Individual ☐ Corporation or other private group entity ☐ Government

4a. The following fee(s) are submitted:

☐ Issue Fee

☐ Publication Fee (No small entity discount permitted)

☐ Advance Order - # of Copies _____

4b. Payment of Fee(s); (Please first reapply any previously paid issue fee shown above)

☐ A check is enclosed.

☐ Payment by credit card. Form PTO-2038 is attached.

☐ The Director is hereby authorized to charge the required fee(s), any deficiency, or credit any overpayment, to Deposit Account Number _____ (enclose an extra copy of this form).

5. Change in Entity Status (from status indicated above)

☐ a. Applicant claims SMALL ENTITY status. See 37 CFR 1.27.

☐ b. Applicant is no longer claiming SMALL ENTITY status. See 37 CFR 1.27(g)(2).

NOTE: The Issue Fee and Publication Fee (if required) will not be accepted from anyone other than the applicant; a registered attorney or agent; or the assignee or other party in interest as shown by the records of the United States Patent and Trademark Office.

Authorized Signature _____

Date _____

Typed or printed name _____

Registration No. _____

This collection of information is required by 37 CFR 1.311. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 12 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, Virginia 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, Virginia 22313-1450.

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Determination of Patent Term Extension under 35 U.S.C. 154 (b)

(application filed after June 7, 1995 but prior to May 29, 2000)

The Patent Term Extension is 0 day(s). Any patent to issue from the above-identified application will include an indication of the 0 day extension on the front page.

If a Continued Prosecution Application (CPA) was filed in the above-identified application, the filing date that determines Patent Term Extension is the filing date of the most recent CPA.

Applicant will be able to obtain more detailed information by accessing the Patent Application Information Retrieval (PAIR) WEB site (<http://pair.uspto.gov>).

Any questions regarding the Patent Term Extension or Adjustment determination should be directed to the Office of Patent Legal Administration at (571)-272-7702. Questions relating to issue and publication fee payments should be directed to the Customer Service Center of the Office of Patent Publication at 1-(888)-786-0101 or (571)-272-4200.

Notice of Allowability

Application No.

09/674,546

Examiner

S. Devi, Ph.D.

Applicant(s)

FRASER ET AL.

Art Unit

1645

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to Applicants' amendment filed 09/11/07.
2. ☒ The allowed claim(s) is/are claims 4 and 22-28, now renumbered as claims 1 and 2-8 respectively.
3. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some* c) ☐ None of the:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).
- * Certified copies not received: _____.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.

THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.

4. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
5. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
- (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
- 1) ☐ hereto or 2) ☐ to Paper No./Mail Date _____.
- (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date _____.
- Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).**
6. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

- | | |
|------------------------------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------|
| 1. <input type="checkbox"/> Notice of References Cited (PTO-892) | 5. <input type="checkbox"/> Notice of Informal Patent Application |
| 2. <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 6. <input type="checkbox"/> Interview Summary (PTO-413),
Paper No./Mail Date _____. |
| 3. <input type="checkbox"/> Information Disclosure Statements (PTO/SB/08),
Paper No./Mail Date _____ | 7. <input checked="" type="checkbox"/> Examiner's Amendment/Comment |
| 4. <input type="checkbox"/> Examiner's Comment Regarding Requirement for Deposit
of Biological Material | 8. <input type="checkbox"/> Examiner's Statement of Reasons for Allowance |
| | 9. <input type="checkbox"/> Other _____. |

Request for Continued Examination

1) A request for continued examination under 37 C.F.R. 1.114, including the fee set forth in 37 C.F.R. 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 C.F.R. 1.114, and the fee set forth in 37 C.F.R. 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 C.F.R. 1.114. Applicants' submission filed on 02/10/09 has been entered.

Applicants' Amendment

2) Acknowledgment is made of Applicants' amendment filed 02/10/09 in response to the final Office Action mailed 08/20/08.

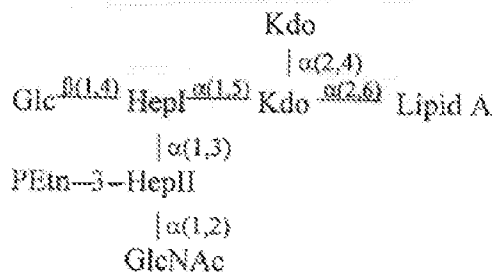
Examiner's Amendment

3) An Examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to Applicants, an amendment may be filed as provided by 37 C.F.R. 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee. The authorization to prepare this Examiner's amendment was provided by Mr. David Hayzer in a telephonic interview on 28 April 2009.

This application has been amended as indicated below:

- (a) Claims 62-100 have been canceled.
- (b) New claims 101-106 have been added as indicated below.

--Claim 101 (New). A method of eliciting in a subject an antibody that binds to the lipopolysaccharide (LPS) inner core of L3, L1, L7, L8, L9, L10, L11 and L12 immunotypes of *Neisseria meningitidis* comprising administering to said subject an immunogenic composition comprising the LPS inner core of *galE* mutant of *Neisseria meningitidis* immunotype L3, wherein the LPS inner core of the *galE* mutant has the formula:



and comprises an LPS inner core epitope wherein a phosphoethanolamine moiety is linked to the 3-position of HepII of the LPS inner core, wherein said epitope is specifically recognized by the monoclonal antibody B5 produced by the hybridoma deposited with the accession number IDAC 260900-1.

Claim 102 (New). The method of claim 101, wherein the LPS inner core of the *galE* mutant does not comprise LPS outer core.

Claim 103 (New). The method of claim 101, wherein the LPS inner core epitope is accessible in the presence of capsule or LPS outer core of said *Neisseria meningitidis*.

Claim 104 (New). The method of claim 101, wherein the antibody elicited does not bind to the LPS inner core of *Neisseria meningitidis* immunotypes L2, L4, L5 and L6.

Claim 105 (New). The method of claim 101, wherein the immunogenic composition is a conjugate.

Claim 106 (New). The method of claim 101, wherein the monoclonal antibody B5 has opsonic activity against a wild type *Neisseria meningitidis* strain comprising an LPS inner core epitope wherein a phosphoethanolamine moiety is linked to the 3-position of HepII of the LPS inner core, and a *galE* mutant thereof.

Status of Claims

- 4) Claims 48-61 have been canceled via the amendment filed 02/10/09.
New claims 62-100 have been added via the amendment filed 02/10/05.
New claims 101-106 have been added via this examiner's amendment.
Claims 101-106 are pending and are under examination.

Oath/Declaration

- 5) The application is objected to because of alterations which have not been initialed and/or dated as is required by 37 CFR 1.52(c). A properly executed oath or declaration which complies with 37 CFR 1.67(a) and identifies the application by application number and filing date is required. See the uninitialed hand-written changes made to the address of inventor Joyce Plested and Michael P. Jennings.

Rejection(s) Moot

- 6) The rejection of claims 48, 55, 62-70, 72-76 and 78-81 made in paragraph 9 of the Office Action mailed 07/30/07 and maintained in paragraph 10 of the Office Action mailed 08/20/08 under 35 U.S.C. § 112, first paragraph, as being non-enabled with regard to the scope, is moot in light of the cancellation of the claims.
- 7) The rejection of claims 48, 55, 70 and 76 made in paragraph 11 of the Office Action mailed 07/30/07 and maintained in paragraph 11 of the Office Action mailed 08/20/08 under 35 U.S.C. § 112, second paragraph, as being indefinite, is moot in light of the cancellation of the claims.
- 8) The rejection of claims 62, 66 and 78 made in paragraph 10(d) of the Office Action mailed 07/30/07 and maintained in paragraph 12 of the Office Action mailed 08/20/08 under 35 U.S.C. § 112, second paragraph, as being indefinite, is moot in light of the cancellation of the claims.
- 9) The rejection of claims 63, 67, 73 and 79 made in paragraph 10(e) of the Office Action mailed 07/30/07 and maintained in paragraph 13 of the Office Action mailed 08/20/08 under 35 U.S.C. § 112, second paragraph, as being indefinite, is moot in light of the cancellation of the claims.
- 10) The rejection of claims 75 and 81 made in paragraph 10(f) of the Office Action mailed 07/30/07 and maintained in paragraph 14 of the Office Action mailed 08/20/08 under 35 U.S.C. § 112, second paragraph, as being indefinite, is moot in light of the cancellation of the claims.
- 11) The rejection of claims 48, 55, 70 and 76 made in paragraph 10(g) of the Office Action mailed 07/30/07 and maintained in paragraph 15 of the Office Action mailed 08/20/08 under 35 U.S.C. § 112, second paragraph, as being indefinite, is moot in light of the cancellation of the claims.
- 12) The rejection of claims 62-69, 72-75 and 78-81 made in paragraph 10(h) of the Office Action mailed 07/30/07 and maintained in paragraph 16 of the Office Action mailed 08/20/08 under 35 U.S.C. § 112, second paragraph, as being indefinite, is moot in light of the cancellation of the claims.
- 13) The rejection of claims 48, 55, 62-70, 72-76 and 78-81 made in paragraph 11 of the Office Action mailed 07/30/07 under 35 U.S.C. § 102(b) as being anticipated by van der Ley *et al.* (*Mol. Microbiol.* 19: 1117-1125, 1996, already of record) as evidenced by Poolman *et al.* (*Infectious Agent and Disease* 4: 13-28, 1995, already of record) and Vogel *et al.* (*Microbiol. Immunol.* 186: 159-

166, October 1997, already of record) or van der Ley *et al.* (*Vaccine* 13: 401-407, 1995, already of record) (van der Ley *et al.*, 1995) and maintained in paragraph 17 of the Office Action mailed 08/20/08 is moot in light of the cancellation of the claims.

Remarks

14) Claims 101-106, now renumbered as claims 1-6 respectively, are allowed.

Claims 101-106 find descriptive support in the paragraph bridging pages 33 and 34; original claims; second full paragraph on page 34; the top panel of Figure 3; Figures 2 and 1; Example 1; and pages 52 and 56 of the instant specification.

15) Papers related to this application may be submitted to Group 1600, AU 1645 by facsimile transmission. The Fax number for submission of amendments, responses and/or papers is (571) 273-8300, which receives transmissions 24 hours a day and 7 days a week.

16) Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAG or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAA system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (in USA or CANADA) or 571-272-1000.

17) Any inquiry concerning this communication or earlier communications from the Examiner should be directed to S. Devi, Ph.D., whose telephone number is (571) 272-0854. A message may be left on the Examiner's voice mail system. The Examiner can normally be reached on Monday to Friday from 7.15 a.m. to 4.15 p.m. except one day each bi-week, which would be disclosed on the Examiner's voice mail system.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's Supervisor, Robert Mondesi, can be reached on (571) 272-0956.

/S. Devi/
Primary Examiner
AU 1645
April, 2009